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The Honorable Brad Wenstrup
Chair
House Oversight Committee
Select Subcommittee on the
Coronavirus Pandemic
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Raul Ruiz
Ranking Member
House Oversight Committee
Select Subcommittee on the
Coronavirus Pandemic
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Wenstrup, Ranking Member Ruiz, and members of the Subcommittee,

Thank you for holding the hearing *Assessing America's Vaccine Safety Systems, Part 2.* I write to the subcommittee as a legal and public health expert to share my perspective on this topic, along with my reflections on our nation's response to the COVID-19 pandemic. Over the course of my career, I have been involved in responses to two global pandemics.

The unknowns associated with unfamiliar pathogens create tremendous uncertainty and necessitate making the best real-time assessments we can with the information we have in the moment. Such emerging threats demand judicious decision-making on the part of our government officials and manufacturers of countermeasures in a fast-paced, high-pressure environment.

In February 2020, it was difficult to anticipate the scope of the threat presented by SARS-CoV-2. Previous threats, such as a 2002-2004 SARS outbreak and the 2009-2010 H1N1 outbreak, were less severe than originally anticipated. But SARS-CoV-2 would be different, as the world and our nation would soon learn. Four years later, COVID-19 has inflicted over 1.1 million deaths and nearly 7 million hospitalizations in the United States alone. Before COVID-19's pandemic-level threat subsided, it would impose a disorienting experience for most Americans, even those who were not infected or did not suffer the tragic loss of a loved one. The toll of human suffering encompassed immense social and economic hardship.

The pandemic response was not a perfect one and not all decisions made were perfect decisions. But the public and private sectors came together, and they acted in good faith, with the best of

intentions to quickly mobilize and defeat the threat with a rapid, scientifically sound vaccination campaign.

As with any emergency response, a proper, candid pandemic postmortem is vital. We must talk about what we can do better next time without distorting facts. We must ask hard questions, take a dispassionate look at the processes that were employed, and examine the successes and failures. This should occur with the singular aim of bettering our ability to respond to future threats and sustaining public trust.

1) Vaccine Injury Compensation and Liability Protection Schemes Are Vital to Compensating the Vaccine-Injured, Maintaining Public Trust and Sustaining Innovation

Like any medical intervention, vaccines can sometimes cause adverse reactions in a small number of people who receive the vaccine. When vaccine-related adverse events do occur, it is imperative that systems are in place to timely and adequately compensate vaccine-injured persons. Our country has a bipartisan history of addressing vaccine safety concerns, compensating the vaccine-injured, protecting manufacturers from liability in order to sustain vaccine innovation, and maintaining our national readiness to combat disease threats. The viability of these systems is, in turn, important to maintaining public trust. It is imperative that this tradition be upheld to protect American lives.

The historical impact of liability risks on manufacturer market participation must not be ignored. Various market forces have contributed to the fragility of the vaccines marketplace, including high regulatory hurdles and high research and development costs.[1] Among these forces is the historical impact of liability risks, discouraging vaccine manufacturers' market participation.[2] When businesses are not profitable or excessive risks pervade their very business model, the businesses eventually go away. This can lead to an eventual lack of competition in the industry and limit the availability of new vaccinations. For instance, these factors led to a decline, over the course of half a century, in the number of vaccine manufacturers – from 26 in 1967, to 17 in 1980 to 5 in 2004.[3] Further, in 1996, the United States market had its recommended childhood vaccines produced by eight firms and laboratories but in 2002, there were only four firms producing childhood vaccines, and similar exits have occurred among manufacturers of adult vaccines.[4]

The threat of liability is particularly concerning for smaller companies such as small biotechnology companies that may hold the keys of scientific promise that will defeat the next pandemic threat. As demonstrated in 2020, companies must be empowered to act boldly, deliberately, and with speed. The overhanging, open-ended threat of litigation and discovery would have a chilling effect on well-intended individuals within these companies attempting to develop and produce safe and effective vaccines. Even if lifesaving technologies may eventually be located or developed,

[1] Jagannath M Muzumdar & Richard R Cline, Vaccine Supply, demand, and policy: a primer, 49 J. AM. PHARM. ASSOC. 4 (2016).
[2] Paul A Offit, Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?, 24 HEALTH AFFAIRS 3 (2005).
[3] *Id.*
[4] Institute of Medicine (US) Committee on the Evaluation of Vaccine Purchase Financing in the United States. FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY, Washington (DC): National Academies Press (US); 2003. 5, Vaccine Supply.

desperately needed speed in vaccine development and production would be sorely lacking. All the while, we risk subjecting ourselves to unnecessarily higher health care costs and economic losses.

Our nation has a bipartisan history of taking action to preserve vaccine innovation and compensate vaccine-injured persons. Vaccine injury compensation and liability protection schemes can alleviate unforeseen harm, help mitigate the financial risks associated with vaccine injury claims and provide a more predictable environment for vaccine manufacturers to innovate and develop new vaccines. In response to the concerning vaccine manufacturer exits outlined above and the need to instill public confidence in vaccine safety and efficacy, Congress has acted twice, under Republican administrations, to establish these necessary schemes.

In 1986, in response to many lawsuits threatening to cause vaccine shortages and reduce U.S. vaccination rates, President Reagan signed the National Childhood Vaccine Injury Act (NCVIA),[5] establishing the National Vaccine Injury Compensation Program (VICP). When President George W. Bush recognized that outbreaks occurring overseas, such as SARS and avian influenza, may reach an unprepared United States, he developed a national pandemic preparedness strategy to prepare for disease outbreak and response.[6] A critical component of that strategy was to call for liability protections for the emergency response enterprise as a whole, including manufacturers of vaccines and other countermeasures deployed during a public health emergency. Consequently, Congress passed the Public Readiness and Emergency Preparedness (PREP) Act,[7] establishing the Countermeasures Injury Compensation Program (CICP). Programs such as the VICP and CICP are vital to maintaining vaccine supply and public confidence, supporting public health goals during normal times and health crises such as pandemics.

Yet, legislation has been introduced in Congress that would permit individuals to sue manufacturers of vaccines for vaccine-related adverse events.[8] This legislation ignores the PREP Act's protection against bad actors, which allows injured parties to bring tort claims directly where a manufacturer acted with willful misconduct.[9] Moreover, eliminating liability protections could unintentionally invite a flood of unfettered and overwhelmingly frivolous lawsuits that would further threaten already fragile vaccine markets.

Compensating the vaccine injured adequately and in a timely manner is imperative. The vaccine-injured cannot be treated as mere collateral damage. Therefore, we must stay the course with the policy balancing act that will provide adequate and timely compensation while sustaining vaccine innovation and public trust. This includes continuous improvements where there are shortcomings. I would, for these reasons, be remiss to overlook the shortcomings of the aforementioned VICP and CICP programs.

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[5] The National Childhood Vaccine Injury Act, *codified at* 42 USC § 300(aa)(1-34) (2007).
[6] The White House, President Outlines Pandemic Influenza Preparations and Response (Nov. 1, 2005), https://georgewbush-whitehouse.archives.gov/news/releases/2005/11/20051101-1.html; MEDICAL COUNTERMEASURES: USA PUBLIC HEALTH SECURITY, https://medicalcountermeasures.gov/ (last visited Mar 19, 2024).
[7] The Public Readiness and Emergency Preparedness (PREP) Act, *codified at* 42 U.S.C. § 247d–6d et. seq.
[8] Let Injured Americans Be Legally Empowered Act, H.R. 7551, 118th Cong. (2023).
[9] The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d–6d et. seq.

The VICP program has seen a significant increase in the number of petitions filed. Over the last decade, the number of petitions filed nearly doubled from 633 petitions in FY 2013 to 1,167 petitions filed in FY 2023.[10] With this influx, the workload of the special masters has increased, however, the statute limits the number of special masters permitted to 8,[11] thereby creating a bottleneck which inevitably delays compensation. Further, currently, each time a new vaccine is approved and recommended, Congress must pass new legislation to apply a 75-cent excise tax to enable HHS to add it to the injury table.[12]

Similarly, the CICP has seen challenges reflected by the number of claims the program is capable of handling and the adequacy of compensation to vaccine-injured persons. Prior to the COVID-19 pandemic, the program received a collective total of approximately 500 claims. Of those 500 claims, three claims were compensated.[13] Given the widespread and immediate response to the COVID-19 pandemic, and the number of individuals being vaccinated at one time, the program has received 12,854 COVID-19 related claims, yet only 2,214 of those claims were adjudicated as of January 1, 2024.[14] 25 of those claims are eligible for compensation but are still pending, and paltry settlements for the first 3 COVID-19 related claims range from $1,032.69 to $2,019.55.[15] The legal authority of the program itself has also been questioned. Many courts have held that the PREP Act cannot preempt state tort claims, creating a slippery slope for vaccine-related claims.[16] It is imperative that these shortcomings are addressed through modernization of these programs.

Two bipartisan bills would address most of these programmatic shortcomings. The *Vaccine Injury Compensation Modernization Act of 2023* (H.R.5142),[17] sponsored by Rep. Lloyd Doggett (D-TX) and Rep. Fred Upton (R-MI) would modernize the VICP with the addition of special masters, extension of term limits to retain experienced special masters, speeding incorporation of newly recommended vaccines, providing an increase in compensation in the event of a vaccine-related death, increasing compensation for pain and suffering, and increases the statute of limitations. The bill would also transfer all pending COVID-19 vaccine-related claims to VICP.

The *Vaccine Access Improvement Act* (H.R.5143),[18] sponsored by Rep. Doggett and Rep. Mike Kelly (R-PA) would amend the Internal Revenue Code to provide authority to add additional vaccines to the list of taxable vaccines. This legislation would ensure that as new vaccines are

[10] Health Resources & Services Administration, HRSA Data & Statistics, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-07-01-22.pdf (last visited Mar 20, 2024).
[11] 42 U.S.C. § 300aa-10 et seq.
[12] *Id.*
[13] Renée J. Gentry & Richard H. Hughes IV, Insult To The Injured: The Case For Modernizing Vaccine Injury Compensation, HEALTH AFFAIRS FOREFRONT (2023), https://www.healthaffairs.org/do/10.1377/forefront.20230718.324863/ (last visited Mar 20, 2024).
[14] Health Resources & Services Administration, Countermeasures Injury Compensation Program Data, https://www.hrsa.gov/cicp/cicp-data (last visited Mar 20, 2024).
[15] Renée J. Gentry & Richard H. Hughes IV, Insult To The Injured: The Case For Modernizing Vaccine Injury Compensation, HEALTH AFFAIRS FOREFRONT (2023), https://www.healthaffairs.org/do/10.1377/forefront.20230718.324863/ (last visited Mar 20, 2024).
[16] Richard H. Hughes IV, Kala Shankle and Chloe Hillard, COVID-19 PREP Act Litigation: The Tip Of The Liability Iceberg, HEALTH AFFAIRS FOREFRONT (2023), https://www.healthaffairs.org/do/10.1377/forefront.20230718.324863/ (last visited Mar 20, 2024).
[17] Vaccine Injury Compensation Modernization Act of 2023, H.R. 5142, 118th Cong. (2023).
[18] Vaccine Access Improvement Act of 2023, H.R. 5143, 118th Cong. (2023).

developed, approved and recommended for use, Americans are able to seek timely compensation without undermining the viability of market participation.

2) Misrepresenting Epidemiology and Vaccine Science Undermines Public Trust, Threatening Human Life

The pandemic followed an unpredictable trajectory of ups and downs in its severity that led to clashes in scientific and lay opinion during the pandemic which continue to this day. SARS-CoV-2 was initially shrouded in mystery and conspiracy theories, and it was scientifically and epidemiologically complex. We could not predict its eventual magnitude. We only knew that most respiratory diseases have a tendency to impact the oldest, youngest and most vulnerable among us the most. Only with time would we understand the full brunt of COVID-19's impact.

We only knew that we must alleviate suffering, mitigate healthcare expenditures, and minimize economic burdens. For over two centuries, vaccination has been the well-established, primary intervention for doing so.

Despite bipartisan clamoring for a vaccine to save human lives, vaccines would become ensnared in election-year political rhetoric. Much-demanded speed was matched with the unprecedented delivery of vaccines in approximately 9 months' time. I fear we have quickly forgotten the initial fear and urgency we collectively felt as public mistrust has sadly been inflamed by public figures and even members of Congress, including some serving on this very committee, promoting misinformation concerning vaccine science:

> *Dr. Birx said she knew the COVID vaccine would not protect against infection, but yet mandates were forced . . .*[19]
>
> *Time and time again, the American people were told by Dr. Fauci and the Biden administration to take the vaccine, and at the time it was experimental at best.*[20]
>
> *Various groups of Americans were . . . forced to choose between their jobs, their religious beliefs, and their health and the vaccine.*[21]

Suggesting that COVID vaccines failed because transmission occurred misrepresents vaccine science. Vaccines are developed and deployed to prevent disease. Unlike many other clinical interventions, we do not administer or receive vaccines simply to protect ourselves. Further, it is misleading to suggest that the singular purpose of vaccination is solely to halt transmission amongst individuals. Neither efficacy nor effectiveness is measured solely by a vaccine's ability to prevent transmission.

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[19] "Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates" (2024), https://www.congress.gov/event/118th-congress/house-event/116287/text.
[20] "Investigating Pandemic Immunity: Acquired, Therapeutic or Both" (2024), https://www.congress.gov/event/118th-congress/house-event/115916/text.
[21] "Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates" (2024), https://www.congress.gov/event/118th-congress/house-event/116287/text.

To determine vaccine efficacy, controlled studies are used to compare outcomes between vaccinated and unvaccinated placebo groups.[22] All COVID-19 vaccines authorized for emergency use and subsequently approved were subjected to these studies. No vaccine, including COVID vaccines, is 100% efficacious. Early in the pandemic, as the disease was evolving and protection was sorely needed, the FDA set its standard for efficacy, stating that it "would expect that a COVID-19 vaccine would prevent disease ***or decrease its severity in at least 50% of people who are vaccinated***."[23]

The evidence used to assess the efficacy of COVID vaccines encompassed primary endpoints such as "risk of infection, symptoms, and severity of COVID-19," along with secondary endpoints like "hospitalization duration, need for supplemental oxygen, and requirement for mechanical ventilation," not disease transmission.[24] These endpoints were evaluated with rigor and painstaking discourse by experts in public meetings.

Effectiveness, a real-world measurement approach which also evaluates the ability of vaccines to provide herd protection,[25] must also be considered.[26] We administer and receive vaccines to build "herd immunity" to protect our friends, family, neighbors and strangers around us, some of whom are unable to protect themselves. By lowering the overall amount of virus that is spread through a given population, herd immunity provides indirect protection against infectious diseases and thereby reduces the number of disease cases (incidence), severity of cases (e.g. hospitalization and complications) and deaths (mortality).[27] In turn, this reduces overall healthcare and economic costs.

Suggesting that vaccines were authorized or mandated without adequate study fails to take into account the circumstances of an urgent threat. In a pandemic, there is such a thing as an acceptable risk. Under the framework established by the Pandemic and All Hazards Preparedness Reauthorization Act,[28] an emergency use authorization (EUA) for vaccines is contingent upon a rigorous assessment that the benefits to public health decidedly surpass any potential risks. Regulatory bodies are empowered to perform a delicate balancing act, weighing the potential risks against the benefits of medical interventions during a crisis. This approach acknowledges that some level of risk is tolerable in exchange for the greater public health good. Ultimately, the overarching aim of issuing an EUA is to affirm that a vaccine is both safe and effective for the broader public, all while addressing the pressing demand for preventive solutions amidst a public health crisis.

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[22] Mitra Saadatian-Elahi, Olaf Horstick, & Robert F. Breiman, et al., Beyond efficacy: The full public health impact of vaccines, 34 VACCINE 9 (2016).
[23] Press Release, U.S. Food and Drug Administration, Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines (June. 30, 2020) (emphasis added), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid
[24] Jonaid Ahmad Malik et al., SARS-COV-2 vaccines: Clinical endpoints and Psychological Perspective: A literature review, 15 JOURNAL OF INFECTION AND PUBLIC HEALTH 5 (2022).
[25] John Clemens, Sunheang Shin & Mohammad Ali, New approaches to the assessment of vaccine herd protection in clinical trials, 11 THE LANCET INFECTIOUS DISEASES 6 (2011).
[26] Mitra Saadatian-Elahi, Olaf Horstick, & Robert F. Breiman, et al., Beyond efficacy: The full public health impact of vaccines, 34 VACCINE 9 (2016).
[27] John Clemens, Sunheang Shin & Mohammad Ali, New approaches to the assessment of vaccine herd protection in clinical trials, 11 THE LANCET INFECTIOUS DISEASES 6 (2011).
[28] *Amending the* Federal Food, Drug and Cosmetic (FD&C) Act, *codified at* 21 U.S.C. 360bbb-3.

Therefore, agencies meticulously evaluate several key factors: the vaccine's efficacy against disease, its capacity to diminish the incidence or severity of cases, and its effectiveness in safeguarding at-risk populations. Considerations extend to the vaccine's role in alleviating the strain on our healthcare infrastructure and curbing outbreaks.

The evaluation of endpoints for COVID vaccines involved a rigorous and meticulous process undertaken by experts, such as the Vaccine and Related Biological Products Advisory Committee (VRBPAC). VRBPAC's public meetings, broadcasted over the Internet, offered a transparent view into the depth of analysis and debate that went into determining the efficacy and safety of COVID vaccines.

Multiple meta-analyses, point to the rigorous study of COVID vaccines, including a high volume of research on vaccine efficacy.[29] One study alone examined 38 million individuals within 14 different countries.[30]

Once a vaccine is authorized or approved and distributed widely, the importance of post-marketing surveillance becomes paramount. Regulatory agencies continue to monitor its safety and efficacy through vigilant post-marketing surveillance. All vaccines are continuously monitored through a variety of systems operating on a large scale, leveraging healthcare data and consumer reports to track vaccine performance in real-time with the ability to identify and investigate rare adverse events that may not have been apparent in pre-licensure clinical trials. This vigilant monitoring continues to ensure that COVID vaccines adhere to safety standards.[31]

Policies promoting vaccination do not equal unconsented, forced medical treatment. Vaccines are simultaneously a clinical and public health intervention and are administered with the intention to prevent disease, not to heal. Nor are vaccines administered to inflict bodily harm. The law has long recognized that the "intentional infliction of harmful bodily contact on the person" constitutes a battery.[32] Therefore, the right of a patient to refuse invasive medical procedures is fundamental. And, in such cases, refusing medical intervention does not endanger others' health or lives. For example, the person who refuses a medically necessary leg amputation does no harm to anyone but herself. The individual who refuses cancer treatment does not inflict cancer on his family. Yet, the unvaccinated person may very well transmit the respiratory illness that takes the life of their elderly neighbor.

The Supreme Court of the United States recognized these principles and the inherent balancing act involved nearly 120 years ago in *Jacobson v Massachusetts,*[33] upholding the authority of states

[29] *See e.g.,* Caifang Zheng, Weihao Shao, Xiaorui Chen, et al., Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis, 114 INTERNATIONAL JOURNAL OF INFECTIOUS DISEASES 252-260 (2022); Jayesh Beladiya, Anup Kumar, Yogesh Vasava, et al., Safety and efficacy of COVID-19 vaccines: A systematic review and meta-analysis of controlled and randomized clinical trials, REVIEWS IN MEDICAL VIROLOGY (2024), https://pubmed.ncbi.nlm.nih.gov/38282394/ (last visited Mar 19, 2024).
[30] Caifang Zheng, Weihao Shao, Xiaorui Chen, et al., Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis, 114 INTERNATIONAL JOURNAL OF INFECTIOUS DISEASES 252-260 (2022).
[31] *See* e.g., Kimberly G. Blumenthal, Neelam A. Phadke & David W. Bates, Safety Surveillance of COVID-19 mRNA Vaccines Through the Vaccine Safety Datalink, 326 JAMA NETWORK 14 (2021); Tom T. Shimabukuro, Michael Nguyen, David Martin & Frank DeStefano, Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS), 33 VACCINE 36 (2021).
[32] Don. S. Smith, Battery in Medical Torts, 16 CLEV.- MARSHALL L. REV. 22 (1967).
[33] *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905).

compel vaccination when they adjudge it necessary, while ***expressly forbidding states to vaccinate "unfit" or medically contraindicated persons***. To this day, no American with a medical contraindication may be forced to be vaccinated.

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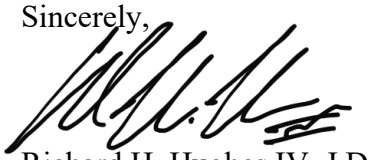
I strongly encourage both Congress and our nation's public health officials to take this moment to self-reflect and to resolve challenges in public confidence in our institutions and science with humility and cautiousness. We cannot simply dismiss public vaccine concerns. Misinformation is unacceptable, as is dismissing misinformation. Facts surrounding epidemiology, vaccine ingredients, vaccine research and development protocols, the population-benefit purpose of vaccinations, must be communicated more effectively to the American people.

Readiness for future emerging disease threats is both a public health and national security imperative. Systems that foster the balance of sufficient liability protection, adequate injury compensation, sustained innovation and public trust are imperative to that readiness. Lawmakers, public figures and individual citizens share a collective responsibility to avoid misrepresentation of science and facts. To otherwise perpetuate or tolerate misinformation stands to jeopardize humankind.

Sincerely,



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